

**5. 510(k) Summary**

K091140  
vidacare

722 Isom Road, San Antonio, TX 78216  
Tel (210) 375 8500 Fax (210) 375 8537  
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**SUMMARY**

Submitter's name: VidaCare Corporation  
Address: 722 Isom Road **OCT 14 2009**  
San Antonio, TX 78216  
Phone: 210-375-8500  
Fax number: 210-375-8537




Name of contact person: Grace Holland  
Regulatory Specialists, Inc  
3722 Ave. Sausalito  
Irvine, CA 92606  
Phone: 949-262-0411  
Fax: 949-552-2821

Date the summary was prepared: Original, April 17, 2009  
Revised, October 10, 2009

Name of the devices: EZ-MIO Distal Tibia, EZ-IO Distal Tibia  
VidaPort Intraosseous Infusions System  
EZ-IO, Humeral Head

Common or usual name: Intraosseous Infusion System  
Classification name: Hypodermic single lumen needle

The legally marketed devices to which we are claiming equivalence  
[807.92(a) (3)]:

 510(k) Number		Trade or Proprietary or Model Name		Manufacturer
1 K062956	1	EZ-MIO, EZ-IO, Distal Tibia	1	Vidacare Corp.
2 K032885	2	VidaPort Intraosseous Infusion System	2	Vidacare Corp.
3 K052408	3	EZ-IO, Humeral Head	3	Vidacare Corp.

## Indications for Use:

### EZ-MIO and EZ-IO:

The EZ-MIO manual driver and EZ-IO power driver provide intraosseous access in the distal tibia of adults when intravenous access is difficult or impossible to obtain in emergent, urgent, or medically necessary cases for up to 24 hours.

### VidaPort Intraosseous Infusion System:

The VidaPort provides intraosseous access in the proximal tibia, when intravenous access is difficult or impossible to obtain in emergent, urgent, or medically necessary cases for up to 24 hours. The device is for use in adult patients only.

### EZ-IO Humeral Head:

The Humeral Head EZ-IO provides intraosseous access in the Humeral Head, when intravenous access is difficult or impossible to obtain in emergent, urgent, or medically necessary cases for up to 24 hours.

Summary of the technological characteristics of our device compared to the predicate devices:

This submission extends the indications for use to include usage in emergent, urgent, or medically necessary cases for up to 24 hours. There have been no changes to the design or components of the devices cleared under 510(k) K062956, K032885 and K052408, and therefore the comparison of technological characteristics listed below are identical.

- Target Population
- Driver Design Features
- Needle Design
- Technique
- Sterility
- Biocompatibility
- Where Used



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Room - WO66-0609  
Silver Spring, MD 20993-0002

Vidacare Corporation  
C/O Ms. Grace Holland  
Regulatory Specialist  
Regulatory Specialist, Incorporated  
3722 Avenue Sausalito  
Irvine, California 92606

OCT 14 2009

Re: K091140

Trade/Device Name: Vidacare<sup>®</sup> Needle for EZ-MIO and EZ-IO, Vidaport Intraosseous  
Infusion System, and EZ-IO Humeral Head

Regulation Number: 21 CFR 880.5570

Regulation Name: Hypodermic Single Lumen Needle

Regulatory Class: II

Product Code: FMI

Dated: September 25, 2009

Received: September 28, 2009

Dear Ms. Holland:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

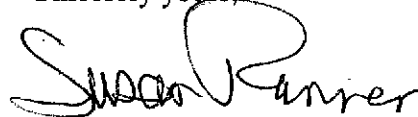
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours

A handwritten signature in black ink that reads "Susan Runner". The signature is fluid and cursive, with the first name "Susan" and last name "Runner" clearly distinguishable.

Susan Runner, D.D.S., M.A.  
Acting Division Director  
Division of Anesthesiology, General Hospital,  
Infection Control and Dental Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

#### 4. Indications for Use Statement

##### Indications for Use

510(k) Number (if known): K091140

Device Name: Vidacare® Needle for EZ-MIO and EZ-IO, VidaPort  
Intraosseous Infusion System, and EZ-IO Humeral Head

##### Indications for Use:

###### EZ-MIO and EZ-IO:

The EZ-MIO manual driver and EZ-IO power driver provide intraosseous access in the distal tibia of adults when intravenous access is difficult or impossible to obtain in emergent, urgent, or medically necessary cases for up to 24 hours.

###### VidaPort Intraosseous Infusion System:

The VidaPort provides intraosseous access in the proximal tibia, when intravenous access is difficult or impossible to obtain in emergent, urgent, or medically necessary cases for up to 24 hours. The device is for use in adult patients only.

###### EZ-IO Humeral Head:

The Humeral Head EZ-IO provides intraosseous access in the Humeral Head, when intravenous access is difficult or impossible to obtain in emergent, urgent, or medically necessary cases for up to 24 hours.

Prescription Use  X  AND/OR Over-The-Counter Use    
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Anthony D. Watson  
(Division Sign-Off)  
Division of Anesthesiology, General Hospital  
Infection Control, Dental Devices

510(k) Number: K091140

Page 1 of 1